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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,188	02/12/2004	Peter James Jenkins	08505.0020	3089

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

PESELEV, ELLI

ART UNIT PAPER NUMBER

1623

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/776,188	Applicant(s) JENKINS ET AL.	
	Examiner Elli Peselev	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 30-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 and 39-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 30-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 30, 2004.

Claims 1-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. for the reasons set forth in the Office Action of January 26, 2005 and the Office Action of May 9, 2005.

Applicant's arguments filed September 9, 2005 have been considered but have not been found persuasive.

Applicant contends that one of ordinary skill would readily appreciate that the disclosure of Example 5 enables the use of Gibberellins alone to treat Type II diabetes mellitus and its complications and associated conditions. Applicant further contends that such enablement is demonstrated in the declaration of Dr. Jenkins. Applicant's arguments and the declaration have been considered but have not been found persuasive. The declaration states that Example 5 enables effective treatment of Type I diabetes by the administration of Gibberellin A3 in combination with a substance such as insulin. This argument has not been found persuasive since none of the claims are limited to the treatment of Type I diabetes with a combination of gibberellins and insulin. Note, for example, that claim 12, encompasses administration of gibberellins

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with fragment derivatives of insulin, IGFs, growth factors and other pharmaceutically compatible anti-diabetic agents. There is no evidence that gibberellins in combination with any other agent, with the exception of insulin, is effective in treating Type I diabetes. Further none of the claims have been limited to the administration of a pharmaceutically effective amount of gibberellin.

With respect to Type II diabetes, the declaration states that administration of small amounts of insulin is shown to replicate the situation of Type II diabetes, where small amounts of insulin may exist. This argument has not been found persuasive because it is not clear from Example 5 that administration of insulin is equivalent to the insulin present in the body at the time of administration of gibberellins. Applicant presented no evidence that administration of insulin and an anti-diabetic compound correlates to the treatment of Type II diabetes with anti-diabetic compound alone.

Applicant also contends that the term "glycosidic" is well known in the art and is disclosed in the Oden'857 patent. This argument has not been found persuasive. In the Oden patent, there is a definition of the term "glycoside" (see column 4, lines 62-67), which is limited to simple sugars. However, in the instant application there is no definition of said term. However, the definition of term "glycoside" is not limited to simple sugars but encompasses oligosaccharides and polysaccharides. Further, it is not clear from the specification and the claims that gibberellins encompassed by the claims are limited to the known gibberellins. Since the term "glycoside" encompasses any organic chemical group derived from a sugar or a starch molecule and reads on so many moieties of different structural formulas and since no guidance is provided in the

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specification on how to choose the specific glycosides which will result a compound having useful utility, it would take an undue amount of experimentation to determine the specific glycosidic derivatives will result in compounds having the desired activity.

Applicant's argument with respect to the terms "allyl" and "amidine" has been found persuasive. With respect to the terms "aryl", "arylalkyl" and "unsaturated or saturated ring", it is not the Examiner's position that the definitions of such terms are not known in the art but that such terms encompass such a large number of possible groups having any number of atoms, that in the absence of any guidance provided in the specification, it would take an undue amount of experimentation to determine the specific groups which will result in compounds having the desired activity.

Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no antecedent basis in claim 40 for the terminology "the organic bases" in claim 41.

Claims 17-29 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Oden (U.S. Patent No. 5,580,857), the International Patent WO 96/20703 or the International Patent No. WO 94/26240 for the reasons set forth in the Office Action of January 25, 2005.

Applicant contends that the term "anti-diabetic" limits the claimed compositions to those that do not contain sugars. This argument has not been found persuasive since

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none the cited prior art requires the presence of sugar in the compositions disclosed. Thus the prior art compositions encompass gibberellin compositions in the absence of sugars.

Claims 1-29 and 39-41 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Davis et al (Journal of the American Medical Association 79:1, 24-26 (January 1989)) for the reasons set forth in the Office Action of January 26, 2005.

Applicant contends that Davis does not teach the treatment of diabetes but relates to the treatment of inflammation. This argument has not been found persuasive. The instant claims encompass administration of gibberellin compounds to a patient having diabetes. Davis also teaches administration of gibberelin compound to a patient having diabetes. In response to applicant's argument that Davis teaches administration of gibberellins for a different purpose, does not detract from the fact that the treatment of diabetes is inherent in the method disclosed by Davis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev


ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200